

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NOVARTIS PHARMACEUTICALS  
CORPORATION,

*Plaintiff,*

v.

ACCORD HEALTHCARE INC., et al.,

*Defendants.*

C.A. No. 18-cv-01043-LPS

**PUBLIC REDACTED VERSION**

**OPENING BRIEF IN SUPPORT OF MYLAN PHARMACEUTICALS INC.'S MOTION  
TO DISMISS FOR IMPROPER VENUE**

**OF COUNSEL:**

Shannon M. Bloodworth  
Brandon M. White  
PERKINS COIE LLP  
700 13th Street NW  
Washington, DC 20001  
(202) 654-6200  
SBloodworth@perkinscoie.com  
BMWhite@perkinscoie.com

Bryan D. Beel, Ph.D.  
PERKINS COIE LLP  
1120 NW Couch Street, 10th Floor  
Portland, OR 97209-4128  
(503) 727-2116  
BBeel@perkinscoie.com

Fredrick L. Cottrell, III (#2555)  
Jason J. Rawnsley (#5379)  
RICHARDS, LAYTON & FINGER, P.A.  
920 North King Street  
Wilmington, Delaware 19801  
(302) 651-7700  
cottrell@rlf.com  
rawnsley@rlf.com

*Attorneys for Mylan Pharmaceuticals Inc.*

Dated: September 7, 2018

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## **I. INTRODUCTION**

This patent infringement suit seeks relief against Mylan Pharmaceuticals Inc. (“MPI”) for MPI’s filing of an abbreviated new drug application (“ANDA”) related to the drug fingolimod in 2014. However, this suit is improper as to MPI because neither MPI nor its ANDA have any connection to Delaware sufficient for Novartis Pharmaceuticals Corp. (“Novartis”) to establish venue over MPI in this District. Therefore, pursuant to Rule 12(b)(3) of the Federal Rules of Civil Procedure and 28 U.S.C. § 1400(b), MPI submits this *Opening Brief in Support of Mylan Pharmaceuticals Inc.’s Motion to Dismiss for Improper Venue*.

More than two years ago, MPI provided notice to Novartis that the late-listed U.S. Patent No. 9,187,405 (“the ’405 patent”) was invalid and would not be infringed by MPI’s proposed ANDA product. Despite this timely notice, Novartis chose not to sue MPI or any other ANDA filer who provided Novartis with similar notice at the time it received these notices in 2016. Instead, Novartis waited more than two years to bring suit against ANDA filers, now burdening the parties and the Court with what will likely be an unnecessarily expedited proceeding.

Novartis’s complaint, however, fails to plead facts sufficient to demonstrate that venue is proper over MPI in Delaware. The complaint concedes that MPI is incorporated in West Virginia and makes no effort to demonstrate that MPI has a regular and established place of business in Delaware – because none exists. Indeed, none of the required elements for establishing venue in a patent infringement case pursuant to § 1400(b) can be met in this case. MPI is not incorporated in Delaware, nor does it have a regular and established place of business there. Therefore, MPI respectfully requests the Court to dismiss the claims against MPI.

## **II. NATURE AND STAGE OF THE PROCEEDINGS**

Novartis has filed at least four nearly identical patent infringement suits against multiple defendants, each alleging that the filing of an ANDA infringed Novartis’s ’405 patent. The

present action was filed on July 16, 2018. D.I. 1. Novartis has not filed any corresponding suit against MPI in any other forum.

No discovery or other substantial steps in this litigation have occurred. While the case is at an early stage, Novartis has made clear its view that the case must be expedited to accommodate the expiration of one of Novartis's patents that is the subject of a series of different litigations, despite Novartis's delay in bringing this suit. *See generally* D.I. 103.

### **III. STATEMENT OF FACTS**

#### **A. Mylan Pharmaceuticals Inc. Is a West Virginia Company**

MPI is a corporation organized and operating under the laws of West Virginia, with its principal place of business in Morgantown, West Virginia. Meckstroth Decl.<sup>1</sup> ¶ 3. MPI is not a newcomer to West Virginia. Indeed, it has operated from West Virginia since its predecessor was founded there in 1961 by two Army buddies looking to give West Virginians access to affordable medicine. Meckstroth Decl. ¶ 4.

MPI does not have any place of business in Delaware, much less a regular and established place of business. Meckstroth Decl. ¶ 6. MPI does not own, lease, or control any manufacturing plants, corporate offices, facilities, or other real property in Delaware. *Id.* MPI has no telephone listings or mailing addresses for any physical location owned, leased, controlled, or occupied by MPI in Delaware. Meckstroth Decl. ¶ 8. MPI has just one employee with a personal residence located in Delaware. Meckstroth Decl. ¶ 9. That employee is a sales representative for certain women's health products with a sales territory that includes the Philadelphia market. *Id.* Her employment is not conditioned on her residence in Delaware, MPI

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<sup>1</sup> Citations to "Meckstroth Decl." are to the accompanying Declaration of Keith Meckstroth in Support of Mylan Pharmaceuticals Inc.'s Motion to Dismiss for Improper Venue concurrently filed herewith.

played no part in her decision to reside in Delaware, and MPI does not reimburse the employee for her residence. *Id.*

#### **B. MPI's Fingolimod ANDA**

MPI filed ANDA No. 208005 [REDACTED], seeking FDA approval for fingolimod 0.5 mg capsules (hereinafter, the "ANDA Product"). Meckstroth Decl. ¶ 10. On April 6, 2016, MPI notified Novartis that MPI had submitted to the FDA ANDA No. 208005 for the ANDA Product. D.I. 1 ¶ 144. MPI prepared this ANDA in West Virginia and electronically filed the ANDA with the FDA in Maryland. Meckstroth Decl. ¶ 10. There has been no manufacture, sale, or offer for sale of the ANDA Product in Delaware. Meckstroth Decl. ¶ 12.

In its 2016 notice letter, MPI notified Novartis that as part of an amendment to its ANDA, MPI had filed a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the late-listed '405 patent, asserting that the patent is invalid and/or will not be infringed by the commercial manufacture, use, and sale of MPI's ANDA Product. D.I. 1 ¶ 145. Despite this timely notice, Novartis did not bring suit on the '405 patent for more than two years.

#### **IV. ARGUMENT**

The Supreme Court's decision in *TC Heartland* reaffirmed that venue in patent cases is governed *solely* by the patent venue statute, 28 U.S.C. § 1400(b). *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1516–17 (2017); *see also UCB, Inc. v. Mylan Techs., Inc.*, No. 17-322-LPS, 2017 WL 5985559, at \*2 (D. Del. Dec. 1, 2017). Section 1400(b) restrictively defines where defendants in a patent case can be sued. For corporations, suit can be brought in either

- (i) the corporation's state of incorporation, or
- (ii) where the corporation has committed an act of infringement and has a regular and established place of business.

*See* 28 U.S.C. § 1400(b). Because MPI is not incorporated in Delaware, has not committed acts of infringement in Delaware, and has no regular and established place of business in Delaware, venue is not proper in this District and the case should be dismissed.

**A. The District of Delaware is Not a Proper Venue for MPI.**

In view of *TC Heartland*, *Cray*, and *In re ZTE*, and the many district court cases applying these decisions, Novartis has not met and cannot meet its burden<sup>2</sup> of demonstrating that venue lies in the District of Delaware over MPI.

**1. MPI Does Not Reside in Delaware.**

The first prong of § 1400(b) provides that a “civil action for patent infringement may be brought in the judicial district where the defendant resides.” In patent infringement cases, a corporation like MPI resides only in its State of incorporation. *TC Heartland*, 137 S. Ct. at 1516-17; *In re BigCommerce, Inc.*, 890 F.3d 978 (Fed. Cir. 2018). Here, MPI’s state of incorporation is not disputed. MPI is a West Virginia corporation. D.I. 1 ¶ 141; *see also Javelin Pharm., Inc. v. Mylan Labs. Ltd.*, No. 16-224-LPS, 2017 WL 5953296, at \*2 (D. Del. Dec. 1, 2017) (holding that MPI does not reside in Delaware for purposes of the first prong of § 1400(b)). Therefore, venue is not proper in this District under the first prong of § 1400(b) with respect to MPI.

**2. MPI Does Not Have a Regular and Established Place of Business in Delaware and Has Not Committed an Act of Infringement There.**

The second prong of § 1400(b) requires that a defendant has committed acts of infringement *and* has a regular and established place of business in the judicial district. 28 U.S.C. § 1400(b); *In re Cray Inc.*, 871 F.3d 1355, 1360 (Fed. Cir. 2017). *Cray* set forth three

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<sup>2</sup> When a defendant challenges venue, the plaintiff bears the burden of establishing proper venue. *In re ZTE (USA), Inc.*, 890 F.3d 1008 (Fed. Cir. 2018).

requirements for determining when a defendant has a regular and established place of business in a district:

- (1) there must be a physical place in the district;
- (2) it must be a regular and established place of business; and
- (3) it must be the place of the defendant.

*Id.* *Cray* emphasized there must be a physical location in the district where business is conducted, and that place must be a regular and established place of business. *Id.* at 1362. MPI has no place of business in Delaware, much less one that meets *Cray*'s stringent requirements.

**a. MPI Does Not Have a Regular and Established Place of Business in Delaware.**

MPI has no place of business in Delaware, much less one that meets the requirements of *Cray*. Meckstroth Decl. ¶ 6. MPI does not own or rent any place of business, manufacturing facility, office, or real property in Delaware *Id.* And Novartis has alleged no facts in support of its conclusory allegation that MPI has a regular and established place of business in Delaware. *See* D.I. 1 at 148. In the absence of a regular and established place of business in this District, venue over MPI does not lie under the second prong of § 1400(b). *See Cray*, 871 F.3d at 1362 (holding that “there must ... be a physical, geographical location in the district from which the business of the defendant is carried out”).

**b. MPI Has Not Committed Any Act of Infringement in Delaware.**

Venue is also not proper under the second prong of § 1400(b) because MPI has not committed any act of infringement in this District. Novartis has alleged that the acts giving rise to this lawsuit stem from MPI's submission of its ANDA to the FDA. D.I. 1 ¶ 147. MPI's preparation of this ANDA and its submission to the FDA do not constitute an act of infringement in Delaware. The preparation and filing of the ANDA did not occur in this District.



Rather, the ANDA was prepared in West Virginia and filed with the FDA in Maryland. Meckstroth Decl. ¶10. Therefore, venue is also not proper in this District under the second jurisdictional prong of § 1400(b).<sup>3</sup>

## V. CONCLUSION

MPI does not reside in Delaware, has not committed any act of infringement in Delaware, and does not have a regular and established business in Delaware. Under *TC Heartland* and *Cray*, and the many cases applying those decisions, venue is not proper in this District over MPI. Defendant respectfully requests that the Court dismiss this action.

### OF COUNSEL:

Shannon M. Bloodworth  
Brandon M. White  
PERKINS COIE LLP  
700 13th Street NW  
Washington, DC 20001  
(202) 654-6200  
SBloodworth@perkinscoie.com  
BMWhite@perkinscoie.com

Bryan D. Beel, Ph.D.  
PERKINS COIE LLP  
1120 NW Couch Street, 10th Floor  
Portland, OR 97209-4128  
(503) 727-2116  
BBeel@perkinscoie.com

Dated: September 7, 2018

/s/ Jason J. Rawnsley

Fredrick L. Cottrell, III (#2555)  
Jason J. Rawnsley (#5379)  
RICHARDS, LAYTON & FINGER, P.A.  
920 North King Street  
Wilmington, Delaware 19801  
(302) 651-7700  
cottrell@rlf.com  
rawnsley@rlf.com

*Attorneys for Mylan Pharmaceuticals Inc.*

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<sup>3</sup> Recognizing the Court's prior ruling on this issue, *Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, No. 17-379-LPS, 2017 WL 3980155, at \*6-13 (D. Del. Sept. 11, 2017), MPI maintains its position that § 1400(b) requires actual acts of infringement to have occurred in Delaware even in Hatch Waxman cases. *See Galderma Labs., L.P. v. Teva Pharm. USA, Inc.*, 290 F. Supp. 3d 599, 606–09 (N.D. Tex. 2017). MPI maintains that it did not commit an act of infringement in Delaware and expressly preserves this issue for appeal. *See Meckstroth Decl.* ¶¶ 10–12.

**CERTIFICATE OF SERVICE**

I hereby certify that on September 7, 2018, true and correct copies of the foregoing document were caused to be filed with the Clerk of Court via CM/ECF, which will send notification of the filing to counsel of record, and I further certify that true and correct copies of the foregoing document were caused to be served on the following counsel of record as indicated:

**VIA ELECTRONIC MAIL**

Jane M. Love, Ph.D.  
Robert Trenchard  
Paul E. Torchia  
GIBSON, DUNN & CRUTCHER LLP  
200 Park Avenue  
New York, NY 10166  
(212) 351-4000  
JLove@gibsondunn.com  
RTrenchard@gibsondunn.com  
PTorchia@gibsondunn.com

**VIA ELECTRONIC MAIL**

Andrew P. Blythe  
GIBSON, DUNN & CRUTCHER LLP  
333 South Grand Avenue  
Los Angeles, CA 90071  
(213) 229-7000  
ABlythe@gibsondunn.com

*Attorneys for Novartis Pharmaceuticals Corporation*

**VIA ELECTRONIC MAIL**

Michael P. Kelly  
Daniel M. Silver  
Benjamin A. Smyth  
McCARTER & ENGLISH, LLP  
Renaissance Centre  
405 N. King Street, 8th Floor  
Wilmington, DE 19801  
(302) 984-6300  
mkelly@mccarter.com  
dsilver@mccarter.com  
bsmyth@mccarter.com

*Attorneys for Novartis Pharmaceuticals Corporation*

/s/ Jason J. Rawnsley

Jason J. Rawnsley (#5379)

rawnsley@rlf.com